

The rejection is incomprehensible especially in view of the teachings at Page 4, Paragraph 0056 and 0059, which state the advantages of the Selis clip. See also the Hall Affidavit at Paragraphs 11a, 11b, 11c, and 11e. If the Examiner is to maintain the rejection on this basis the Examiner must clarify the rejection and support the arguments with facts, supported by evidence, and case law.<sup>1</sup> Moreover, the Examiner is taking a conflicting position; previously the Examiner stated that the Selis Application was patentable over Hoyns and now the Examiner is rejecting the Selis Application based on Hoyns.<sup>2</sup>

Further, the Office Action states that, "Hoyns fails to disclose the first ends of the first and second arc segments project in a direction away from the second ends of the first and second arc segments." Furthermore, Applicants believe that; Hoyns does fail to teach a first and second arc segments that project in a direction away from the second ends of the first and second arc segments because if the clip was oriented in this manner it would not spring or clamp and would not operate in the manner taught by Hoyns. However, the Office Action continues and states that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to orient the ends as claimed." This argument cannot succeed in view of the facts listed in the first response to the Office Action, the Hall Affidavit, and this response (detailed below), which are supported by evidence and case law.

#### Rejection Cannot Stand in View of Non-Obviousness

The Hall Affidavit sets forth considerable objective evidence of nonobviousness, which the Examiner must consider. *Graham v. John Deere & Co.*, 383 U.S. 1 (1966), *In re Sernaker*, 702 F.2d 989 (Fed. Cir. 1983). The Court stated in *Graham* that "[o]bjective considerations such as failure by others to solve the problem and copying 'may often be the most probative and cogent evidence' of nonobviousness." *Advanced Display*

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<sup>1</sup> As mentioned previously it is not understood whether the Examiner is attacking the species elected as compared with the other disclosed species. If so, then this is believed to be erroneous and unsupported by law.

<sup>2</sup> Currently this case is being rejected by Hoyns et al. (6,766,186). In a previous Office Action, dated March 06, 2007, Hoyns was cited as a reference and the reference was discussed at length with both the Examiner and the Examiner's Supervisor, Anh Tuan Nguyen, during an in-person interview. After this in-person interview the case was allowed, over the Hoyns reference stating:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hoyns et al. (Patent No. 6,766,186 B1) discloses a post biopsy tissue marker (Figure 14). It is noted that the first ends (66) of the first (61) and second (62) arc segments project in a direction towards the second ends (66) of the first (61) and second (62) arc segments, therefore, Hoyns et al. does not read on claim 61 (emphasis added)

The issue fee was subsequently paid. Due to the withdrawal of issue and a Final Office Action based on the Hoyns reference, the Applicant is being unduly burdened with additional expenses. The Applicant is a sole inventor with finite resources.

*Systems, Inc. v. Kent State University*, 212 F.3d 1272, 54 USPQ2d 1673, 1682 (Fed. Cir. 2000) (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538, 218 USPQ 871, 879 (Fed. Cir. 1983)). Applicant invented and applied for a patent application on his clip. Subsequently, a manufacturer copied this clip and broadly distributed the clip for sale. This manufacturer developed and sold multiple different clips before changing and selling the Applicant's clip. "The copying of an invention may constitute evidence that the invention is not an obvious one. . . . This would be particularly true where the copyist had itself attempted for a substantial length of time to design a similar device, and had failed."). *Advanced Display Systems, Inc. v. Kent State University*, 212 F.3d 1272, 54 USPQ2d 1673, 1682 (Fed. Cir. 2000) (quoting *Vandenberg v. Dairy Equipment Co.*, 740 F.2d 1560, 1567, 224 USPQ 195, 199 (Fed. Cir. 1984)).

The Hall Affidavit is objective evidence of non-obviousness and supports the patentability of the present claims. The Hall Affidavit provides that the subject technology is the same clip as shown in the Selis Application and that sales are already being made. As stated in the Hall Affidavit the technology has success despite the teachings of Hoyns et al., where Hoyns teaches that migration can only be prevented by the clip springing or clamping.

The Hall Affidavit establishes that the subject technology has been commercialized and that significant sales have already been made. The technology overcomes skepticism in the art by solving a problem without using springing or clamping. See *In re Dow Chem. Co.*, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988). Moreover, the Selis clip solves this problem despite the fact that clamping was thought to be the only way to prevent migration. Support for this statement is found in the Hoyns patent Column 1, lines 54-57 where Hoyns states, "Thus, there is a need for a marker which automatically mechanically **attaches** to the target tissues upon being deployed, without the need for intervention by the surgeon." (Emphasis Added) And in column 2, lines 42-44 where Hoyns states, "Upon the marker exiting the forward end of the needle the barbs **spring** outward, anchoring the marker to the tissue." (Emphasis Added)

As stated by the Court in the case of *In re Rouffet*, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998):

The secondary considerations are also essential components of the obviousness determination. See *In re Emert*, 124 F.3d 1458, 1462, 44 USPQ2d 1149, 1153 (Fed.Cir. 1997) ("Without Emert providing rebuttal evidence, this prima facie case of obviousness must stand."). This objective evidence of nonobviousness includes copying, long felt but

unsolved need, failure of others, See *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 [ 148 USPQ 459 ] (1966), commercial success, see *In re Huang*, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689-90 (Fed.Cir. 1996), unexpected results created by the claimed invention, unexpected properties of the claimed invention, see *In re Mayne*, 104 F.3d 1339, 1342, 41 USPQ2d 1451, 1454 (Fed.Cir. 1997); *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (Fed.Cir. 1990), licenses showing industry respect for the invention, see *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed.Cir. 1997); *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 316, 227 USPQ 766, 771 (Fed.Cir. 1985), and skepticism of skilled artisans before the invention, see *In re Dow Chem. Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1532 (Fed.Cir. 1988).

As the evidence supports, Applicant invented the clip by proceeding against accepted wisdom. See *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed.Cir. 1997)("Indeed, the years of use of salty bait and of plastic lures, without combining their properties, weighs on the side of unobviousness of the combination. Mr. Larew persisted against the accepted wisdom, and succeeded. The evidence that the combination was not viewed as technically feasible must be considered, for conventional wisdom that a combination should not be made is evidence of unobviousness. See *In re Hedges*, 783 F.2d 1038, 1041, 228 USPQ 685, 687 (Fed.Cir. 1986) (proceeding against accepted wisdom is evidence of unobviousness).")

Also, at least one company has subsequently adopted a clip as disclosed in the Selis Application. The recent introductions into the market place of this clip also appears to pay tribute to the inventive concept. It has long been held that evidence of nonobviousness must be considered by the Examiner. *In re Sernaker*, 702 F.2d 989 (Fed. Cir. 1983)("all evidence of nonobviousness must be considered when assessing patentability") Accordingly, even if the Examiner has established a prima facie case of obviousness, Applicant has overcome the rejections by the amendments made in the first response to the Office Action and have rebutted the obviousness rejection via the evidence in the Hall Affidavit. Withdrawal of the pending rejections and allowance of the claims, therefore, is respectfully requested.

The present invention is an example of an elegantly simple solution to problems faced in the diagnosis and treatment of cancerous or abnormal growths. As stated in *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1446 (Fed. Cir. 1992), "simplicity is not inimical to patentability." Citing *Goodyear Tire & Rubber Co. v. Ray-O-Vac Co.*, 321 U.S. 275, 279, 60 U.S.P.Q. 386, 388 (1944) (simplicity of itself does not negative invention); *Panduit*

*Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1572, 1 U.S.P.Q.2d 1593, 1600 (Fed. Cir.1987) (the patent system is not foreclosed to those who make simple inventions), *cert. denied.*, 481 U.S. 1052 (1987).

As stated in, *In re Sullivan*, 84 USPQ2d 1034, 1040 and 1038 (Fed. Cir. 2007) it is clear that:

It is well settled that the PTO "bears the initial burden of presenting a prima facie case of unpatentability... . However, when a prima facie case is made, the burden shifts to the applicant to come forward with evidence and/or argument supporting patentability." *In re Glaug*, 283 F.3d 1335, 1338 [62 USPQ2d 1151] (Fed. Cir. 2002). Rebuttal evidence is "merely a showing of facts supporting the opposite conclusion." *In re Piasecki*, 745 F.2d 1468, 1472 [223 USPQ 785] (Fed. Cir. 1984). Evidence rebutting a prima facie case of obviousness can include: "evidence of unexpected results," *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1369 [82 USPQ2d 1321] (Fed. Cir. 2007), evidence "that the prior art teaches away from the claimed invention in any material respect," *In re Peterson*, 315 F.3d 1325, 1331 [65 USPQ2d 1379] (Fed. Cir. 2003), and evidence of secondary considerations, such as commercial success and long-felt but unresolved needs, *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 [51 USPQ2d 1385] (Fed. Cir. 1999). When a patent applicant puts forth rebuttal evidence, the Board must consider that evidence. See *In re Soni*, 54 F.3d 746, 750 [34 USPQ2d 1684] (Fed. Cir. 1995) (stating that "all evidence of nonobviousness must be considered when assessing patentability"); *In re Sernaker*, 702 F.2d 989, 996 [217 USPQ 1] (Fed. Cir. 1983)

As stated in *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 56 USPQ2d 1456, 1463 (Fed. Cir. 2000), the Examiner must presume that the commercial success of an already marketed invention has a presumed nexus to the claims and it is their burden to show otherwise:

A nexus between commercial success and the claimed features is required. See *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571, 41 USPQ2d 1641, 1647 (Fed. Cir. 1997); *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392, 7 USPQ2d 1222, 1226 (Fed. Cir. 1988). However, if the marketed product embodies the claimed features, and is coextensive with them, then a nexus is presumed and the burden shifts to the party asserting obviousness to present evidence to rebut the presumed nexus. See *J.T. Eaton*, 106 F.3d at 1571, 41 USPQ2d at 1647; *Demaco*, 851 F.2d at 1392-93, 7 USPQ2d at 1226. The presumed nexus cannot be rebutted with mere argument; evidence must be put forth. See *Demaco*, 851 F.2d at 1393, 7 USPQ2d at 1226-27 ("It is thus the task of the challenger to adduce evidence .... [A]rgument and conjecture are insufficient.") (internal quotations and citation omitted). In this case, a nexus should be presumed because the Capri encompasses the claimed features. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 56 USPQ2d 1456, 1463 (Fed. Cir. 2000).

The Office Action further states that Hoyns does not teach the Selis clip; however, it would have been obvious to one having skill in the art to create the Selis clip. This argument fails for three reasons. First, the proposed modification cannot render the prior art unsatisfactory for its intended purpose. See MPEP 2143.01. If the Hoyns clip was modified to look like the Selis clip the Hoyns clip would not spring or clamp and it would no longer be satisfactory for its intended purpose. Second, the Office Action appears to suggest that there are a finite number of ways the Hoyns clip could be modified. This argument cannot succeed because there is no motivation to alter the Hoyns clip and there are not a finite number of predictable ways to modify the Hoyns clip. Third, the Hall Affidavit in section 11(d) states that there is "a virtually endless number of variations that might be pursued." The Hall Affidavit goes on to list just some of the possible modification that could be done such as, "adopting an A-symmetrical geometry, using dissimilar materials for the barbs, varying the material properties along the device, varying the dimensions of the device, [and] varying orientation of the barbs in three-dimensional space." In view of the facts supported by evidence and case law the obviousness rejection cannot be maintained and the application should be allowed.

### CONCLUSIONS

In view of Applicant's remarks, the Examiner's previously presented rejections are believed to be rendered moot. Accordingly, Applicant submits that the present application is in condition for allowance and requests that the Examiner pass the case to issue at the earliest convenience. Should the Examiner have any question or wish to further discuss this application, Applicant requests that the Examiner contact the undersigned at (248) 292-2920.

If for some reason Applicant has not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent the abandonment of this application, please consider this as a request for an extension for the required time period and/or authorization to charge Deposit Account No. 50-1097 for any fee which may be due.

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